

Remarks:

Applicant has carefully studied the non-final Examiner's Action mailed 12/30/2004, having a shortened statutory period for response set to expire 03/30/2005, and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings and numbered paragraphs that correspond to the centered headings and paragraph numbering employed by the Office, to ensure full response on the merits to each finding of the Office.

Claim Rejections – 35 U.S.C. § 102

1. Applicant acknowledges the quotation of 35 U.S.C. § 102(b).
2. Claims 1-4, 32-36, 38-45, and 46-84 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Fogerty et al. (hereinafter "Fogerty"). Reconsideration and withdrawal of this ground of rejection is requested because the Fogerty device includes no marker having an anti-migration attachment means secured thereto. Moreover, the Fogerty device does not engage the tissue to be biopsied or excised and therefore teaches away from Applicants' contribution to the art.

More particularly, as to claims 1, 46, 52, 78, 79, and 81-84, the Office contends that Fogerty discloses an apparatus and method for marking a biopsy site that includes: 1) a marker at the distal end of the catheter; and 2) an attachment member that can be configured to form a J-hook or barb and be fixedly attached to a target tissue site where a biopsy is being performed. The only device at the distal end of delivery catheter 300 is locator element 200. If locator element 200 is the marker, what part is the attachment means? Conversely, if locator element 200 is the attachment means, what part is the marker? Clearly, locator element 200 combines the marker and attachment means functions into one element because it is formed of a memory material and therefore curls under its inherent bias into a loop when it is pushed from the confines of delivery catheter 300. Accordingly, a marker that serves as its own anti-migration means (it is difficult for a loop-shaped element to migrate in tissue) cannot be characterized, in

fairness to Applicants, as including a marker and an attachment means as independent elements as claimed by Applicants.

Nor does Fogerty teach or suggest an attachment means secured to a leading end of a marker as claimed by Applicants.

As explained by Fogerty in lines 57-66 of column 15:

As the distal end of the locator element 200 is deployed beyond the distal end of delivery tube 300 into the tissue of interest by pusher assembly 700, locator element 200 naturally assumes a second, substantially arcuate or curvilinear profile discussed above as it penetrates tissue and defines a tissue border along a path. The tissue border defines a tissue volume containing the targeted lesion that is to be excised. Preferably, locator element 200 does not penetrate the volume as it is deployed.

Locator element 200 is disposed inside a body, but it has a trailing end that protrudes from the surface of the skin and which is therefore outside the body. As disclosed in column 4, lines 15-22:

An optional suture, flexible wire, or cable may be affixed to a proximal end of the locator element to extend through the tissue volume and outside the skin surface when deployed in the body.

The wire that protrudes from the patient's body (typically, from a breast) is unacceptable to patients because there is usually a substantial amount of time between the placing of locator element 200 into the body and the day of surgery. Patients do not want to spend that time with a wire such as the Fogerty wire extending from their body. For that reason, tissue markers that do not have such a protruding wire have been developed because they are positioned wholly inside the body and therefore are not unsightly. However, prior art tissue markers migrate after their placement and thus lack utility because they do not mark the biopsy or surgery site after such migration has occurred. Applicants' inventive structure is designed to engage the tissue to be surgically removed or to be subjected to further biopsy procedures so that the marker does not migrate. Such a marker is neither taught nor suggested by a wire having a leading end that encircles a lesion without engaging it and which has a trailing end that protrudes from a patient's body.

More specifically, Applicants' contribution to the art includes a marker having a biodegradable part and a permanent, metallic part for permanent marking. The metallic part

prevents migration of the biodegradable part and prevents its own migration after the biodegradable part has been bioabsorbed.

The purported "optional" aspect of the wire that protrudes from the patient's body in the Fogerty device is questionable. The physician uses such wire as a guide to the site of the lesion to be excised or further biopsied.

It is also noted that locator element 200 lacks a barb. It relies upon encircling the lesion as its anti-migration means. This anti-migration technique teaches away from Applicants' hook.

In view of the allowance of independent method claim 5, independent apparatus claim 1 is amended to recite Applicants' structure with the same level of detail as recited in said allowed method claim. Claim 1, as amended, is therefore the apparatus equivalent of the method recited in claim 5 and therefore said claim 1 is in condition for allowance.

Dependent claims 2-4 are allowable as a matter of law upon the allowance of claim 1, currently amended.

As to independent claim 46, Fogerty neither teaches nor suggests a marker having two parts, one of which is the marker proper and the other of which is an attachment means having a first part secured to the marker and a second part adapted to engage tissue. Although claim 46 is broader than claim 1, it is clearly allowable over Fogerty. The amendment to claim 46 improves the form thereof but is not needed to define over Fogerty.

Independent claim 52 differs from claim 46 merely because it recites an anchor instead of an attachment means. Thus, claim 52 as currently amended is allowable over Fogerty for the same reasons that claim 46 is allowable over Fogerty.

Claim 78 depends from independent claim 72, discussed below, and is allowable as a matter of law upon allowance of said independent claim 72.

Claim 79 is an independent method claim that is amended to include the limitations of now-cancelled claims 80-84. Claim 79, currently amended, recites an invention that is clearly neither taught nor suggested by Fogerty. The Fogerty structure includes no catheter having a side port from which unfolds a barbed anchor that is attached to a marker.

The cancellation of claims 81-84 has rendered moot the rejection of said claims.

As to claims 32, 38, 44, 58, 64, and 72, the Office contends that Fogerty discloses a "biopsy needle in the catheter (that) is delivered to the tissue site via plunger disposed within a lumen as shown in figures 11-17." However, said figures depict drive tube 400 that ensleeves

deployment tube 300 that ensleeeves locator element 200. Pusher assembly 700 pushes locator element 200 out of deployment tube 300. Locator element 200, as noted above, neither teaches nor suggests a tissue marker having a barbed attachment means secured thereto and extending therefrom. Therefore the Fogerty pusher assembly 700 is a representative sample of the vast prior art for tube-in-tube plunger assemblies, but neither Fogerty nor any other prior art disclosure employs a plunger assembly to deploy Applicants' unique tissue marker and attachment means.

Applicants specifically traverse the rejection of claim 32 by pointing out that independent apparatus claim 32 recites a structure that can be used when performing the steps of allowed independent method claim 37. Accordingly, the rejection of independent apparatus claim 32 is believed to have been made inadvertently. More specifically, the ramp member recited in claim 32 has no counterpart in the Fogerty structure. The curvature in Fogerty locating element 200 is not ramp-imparted.

As to independent apparatus claim 38, said claim recites the limitations of the novel tissue marker having an attachment means the trailing end of which is secured to the tissue marker and the leading end of which is adapted to engage tissue, and said claim further recites the limitations of the coaxial needle having a lumen within which the tissue marker is positioned and the plunger used to push the tissue marker from said lumen so that said leading end engages tissue adjacent a biopsy site. The limitations concerning the catheter and the plunger are old in the art but when combined with the limitations concerning the novel tissue marker, said claim 38 is allowable.

Similarly, independent apparatus claim 44 includes the limitations of independent apparatus claim 38, but adds the further limitation that a barb is formed in the leading end of the attachment means. Therefore it has a narrower scope than claim 38 and is allowable for that reason in view of the allowability of said claim 38.

Independent claim 58, currently amended, is broad in scope but does not exceed the breadth to which the present invention is entitled. Instead of reciting an attachment means having a trailing end secured to a tissue marker and a leading end adapted to engage tissue, claim 58 recites a tissue marker and a barb having a first part secured to the tissue marker and a second part adapted to engage tissue. This frees the invention of the limitation that the barbed attachment means must have a trailing end and a leading end.

Independent apparatus claim 64 is currently amended so that it has a form that is improved over its original form. It now clearly recites the embodiment of Figs. 37-40. Fogerty neither teaches nor suggests a delivery catheter having a side port and a ramp disposed at the distal end of the delivery catheter that guides a plunger-pushed tissue marker having an anchor up the ramp and out the side port.

Independent apparatus claim 72 is currently amended to correct a typographical error. It recites a marker disposed within the lumen of a needle, as distinguished from a delivery catheter, but in all other respects has essentially the same scope as independent claim 38 and is allowable for the same reasons that independent claim 38 is allowable.

As to dependent claims 2-4, 33-36, 39-42, 47-50, 53-56, 59-62, 65-71, and 73-76, the amendment of independent claim 1 has placed dependent claims 2-4 in condition for allowance, the allowability of independent claims 32 and 38 for the reasons already stated places dependent claims 33-36 and 39-42, respectively, into condition for allowance, and the amendments made to independent claims 46, 52, 58, 64, and 72 places dependent claims 47-50, 53-56, 59-62, 65-71, and 73-76, respectively, into condition for allowance.

The Office contends in connection with this group of dependent claims that "Fogerty et al. disclose that the locator or marker element is made of biocompatible or biologically absorbable material with attachment by metal wires, polymers, etc. (col. 13, lines 30-58)." However, Fogerty et al. merely disclose that a biocompatible material may be used to electrically insulate the edges of locator element 200 to facilitate cutting of tissue with RF energy. Such insulation cannot be characterized, in fairness to Applicants, as being a tissue marker.

As to dependent claims 43, 45, 51, 57, 63, 77, and 80, the Office contends that Fogerty discloses a flexible and resilient marker attachment member that can be configured to a desirable shape. However, Fogerty does not teach or suggest that locating element 200 may be configured into any desirable shape. To the contrary, Fogerty teaches that locating element 200 "exhibits shape memory characteristics. Alternatively, the locator element may be plastically deformed to take an arcuate or curvilinear shape during deployment through a die." (col. 3, lines 59-62) All embodiments of Fogerty teach an arcuate locating element 200 that circumscribes a tumor, lesion, or other foreign object to be surgically removed. Accordingly, one of ordinary skill in this art would have been impelled away from Applicants' invention by the Fogerty disclosure.

Claims 43, 45, 51, 57, 63, 77, and 80 depend from independent claims 38, 44, 46, 52, 58, 72, and 79, respectively, and are therefore allowable as a matter of law upon the allowance of their respective independent claims.

Allowable Subject Matter

3. Claims 5-31 and 37 stand allowed. As to independent claim 5, Applicants acknowledge that Fogerty et al. do not teach or suggest a method of marking tissue by attaching a straight attachment means to a leading end of a marker, placing an anvil having a concave bottom formed therein at the leading end of a catheter having a side port, inserting the catheter into the lumen of a biopsy needle having a side port until the respective side ports of the catheter and needle align with one another, introducing a vacuum into the lumen of the catheter so that tissue is pulled into the lumen of the catheter through the aligned side ports, advancing the marker from a trailing end of the catheter toward the anvil so that the straight attachment means impales the tissue in the lumen of the catheter and is then bent upon encountering the concave bottom of the anvil, thereby forming a hook that anchors the marker to tissue, and withdrawing the catheter and needle, all as recited in allowed independent claim 5 and as depicted in Figs. 2-7.

Applicants further acknowledge that Fogerty et al. do not teach or suggest the apparatus of allowed independent claim 6 including a clip having opposed normally closed jaws that are opened by a second, leading part of a plunger having a reduced diameter relative to a first, trailing part of the plunger having a diameter equal to that of a tissue marker disposed in the lumen of a catheter where the reduced diameter first part has a pointed leading end for engaging tissue and where the jaws of the clip are opened when the second part of the plunger is inserted sequentially through a bore formed in a marker, through a bore formed in the trailing end of the jaws, and between the jaws to open them, and where the jaws close, engaging tissue, under an inherent bias when the plunger is withdrawn, as depicted in Figs. 8-14.

Applicants further acknowledge that Fogerty et al. do not teach or suggest the method of using the clip of claim 6 as recited in allowed independent claim 11.

Nor do Fogerty et al. teach or suggest the invention recited in independent apparatus claim 12 and independent method claim 18 as depicted in Figs. 15-22, where the jaws of the clip are normally open, where the clip has a cross-shaped bore formed in its trailing end, where an inner plunger has a cross-shaped middle part, where each jaw of the clip has a beveled

outwardly-extending protuberance formed thereon, where the jaws are closed, to engage tissue, when the beveled ends are engaged and driven toward one another by the leading end of a marker that is displaced toward said beveled ends by an outer plunger, where the cross-shaped middle part of the inner plunger is initially aligned with the cross-shaped bore of the clip so that the inner plunger may be advanced in a trailing-to-leading direction through said bore of said clip and then rotationally misaligned with the cross-shaped bore of the clip to prevent trailing-to-leading displacement of the clip as the outer plunger and marker are advanced in a trailing-to-leading direction, and where the inner plunger is thereafter rotated so that its middle part again aligns with the bore of the clip so that said inner plunger may be withdrawn.

Applicants also acknowledge that Fogerty neither teaches nor suggests the embodiment recited in independent apparatus claim 20 and independent method claim 25 and depicted in Figs. 24-29.

Moreover, Applicants acknowledge that Fogerty neither teaches nor suggests the embodiment recited in independent apparatus claim 26 and independent method claim 31 and depicted in Figs. 30-36.

Applicants further acknowledge that Fogerty neither teaches nor suggests the embodiment recited in independent apparatus claim 32 and independent method claim 37 and depicted in Figs. 37-40. Claim 37 stands allowed but claim 32 stands rejected. However, in view of the allowance of independent method claim 37, it is believed that the Office has inadvertently rejected independent apparatus claim 32 and its dependent claims 33-36 because said apparatus claims recite the structure required to perform the steps recited in the method claims.

Conclusion

4. Applicants agree that the art made of record and not relied upon is not more pertinent to the claimed invention than the art cited.

If the Office is not fully persuaded as to the merits of Applicants' position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested. Applicants thank the Office for its careful examination of this important patent application.